

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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JESSICA GUSTAVSON and JEFFREY  
GUSTAVSON, individually, and as the natural  
parents of SHAWN GUSTAVSON

CAUSE NO. \_\_\_\_\_

Plaintiffs,

JURY TRIAL DEMANDED

v.

Honorable Cynthia M. Rufe

PFIZER, INC., a Delaware Corporation;  
PFIZER INTERNATIONAL LLC, a New  
York Corporation; J.B. ROERIG &  
COMPANY, a Division of Pfizer, Inc.; and  
GREENSTONE, LLC, fka GREENSTONE,  
LTD.,

MDL DOCKET NO.  
12-MD-2342

Defendants.  
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**COMPLAINT**

1. Jessica Gustavson ("Mother Plaintiff") and Jeffrey Gustavson ("Father Plaintiff"), (collectively "Parent Plaintiffs") reside at 8329 Chickasaw Street, Fort Benning, GA 31905, and are the natural parents of Shawn Gustavson ("Minor Plaintiff") by and through their undersigned counsel, hereby submit this Complaint against Defendants PFIZER, INC., PFIZER INTERNATIONAL, LLC, J.B. ROERIG & COMPANY, and GREENSTONE, LLC ("Defendants").

2. "Plaintiffs" when used in this complaint collectively refers to Plaintiffs, Jessica Gustavson and Jeffrey Gustavson, individually and as the natural parents and guardians of Shawn Gustavson, a minor.

3. As more specifically pleaded below, Plaintiffs maintain that the pharmaceutical drug ZOLOFT® and/or sertraline hydrochloride (hereinafter collectively "Zoloft") is defective,

dangerous to human health, unfit and unsuitable to be marketed and sold in commerce and lacked proper warnings as to the dangers associated with its use.

### **I. PLAINTIFFS**

1. Plaintiffs, Jessica Gustavson and Jeffrey Gustavson, are the biological parents and guardians of Shawn Gustavson, who was born on November 6, 2004.

2. The Minor Plaintiff was born November 6, 2004, with congenital birth defects known as bladder exstrophy, epispadias, dorsal chordee, macrocephaly, and other related conditions as a result of Mother Plaintiff's ingestion of Zoloft manufactured by Pfizer, Inc.

3. Parent Plaintiffs bring this action on behalf of themselves as individuals and on behalf of Minor Plaintiff to recover medical and other expenses related to treatment resulting from Minor Plaintiff's birth defects, disorders and/or related illnesses and for general and special damages, including punitive damages, and such other relief as requested herein for injuries suffered by Minor Plaintiff as a direct result of the Mother Plaintiff's ingestion of Zoloft.

### **II. DEFENDANTS**

4. Defendant, Pfizer, Inc. was and still is a duly existing corporation under and by virtue of the laws of the State of Delaware with its principal place of business in the New York City, New York. At all times hereinafter mentioned, defendant Pfizer, Inc. was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public the drug ZOLOFT® (known generically as sertraline), an antidepressant, throughout the United States. Pfizer may be served with process by serving its registered agent CT Corporation, 116 Pine Street, Suite 320, Harrisburg, PA 17101.

5. Defendant, Pfizer International LLC, a New York Corporation, was and still is a duly existing corporation under and by virtue of the laws of the State of New York with its

principal place of business in New York, New York. At all times hereinafter mentioned, defendant Pfizer International LLC was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public the drug ZOLOFT® (known generically as sertraline), an antidepressant, throughout the United States. Pfizer International may be served with process by serving its registered agent CT Corporation System, 111 Eighth Avenue, New York, NY 10011.

6. Defendant, J.B. Roerig & Company ("Roerig") is a division of Pfizer Inc. It is a duly existing corporation under and by virtue of the laws of the State of Delaware with its principal place of business in New York, New York. At all times hereinafter mentioned, defendant Roerig was, and still is, a pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution and marketing of pharmaceuticals for distribution, sale and use by the general public the drug Zoloft (known generically as sertraline), an antidepressant, throughout the United States. Roerig may be served with process by serving Pfizer Inc.'s registered agent CT Corporation System, 111 Eighth Avenue, New York, NY 10011.

7. Defendant, GREENSTONE, LLC, formerly known as GREENSTONE, LTD., is a wholly owned subsidiary of PFIZER, INC., which was and still is a corporation duly existing under and by virtue of the laws of the State of Delaware with its principal place of business in Peapack, New Jersey. GREENSTONE, LLC, may be served with process by serving via certified mail addressed to Greenstone LLC, The Corporation Trust Company, 1209 Orange St., Wilmington, Delaware 19801.

8. For purposes of this Complaint "Defendants" as used herein refers to Defendants, PFIZER, INC., PFIZER INTERNATIONAL, LLC, J.B. ROERIG & COMPANY, and GREENSTONE, LLC.

### **III. JURISDICTION AND VENUE**

9. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

10. At all times material to this action, the parties to this litigation are citizens of different state and this Court has original jurisdiction pursuant to 28 USCA § 1332.

11. This is an action for damages which exceeds the sum of seventy-five thousand dollars (\$75,000.00).

12. The United States District Court for the Eastern District of Pennsylvania is the site of Multidistrict Litigation regarding claims of injury for Zoloft (Sertraline Hydrochloride) Docket No. 12-MD-2342.

13. Pursuant to Pretrial Order No. 11 (Doc. No. 264) the Honorable Cynthia Rufe on October 17, 2012 indicated that any case that would be subject to transfer to the MDL proceedings may file the case directly in the Eastern District of Pennsylvania. This is a case that would be subject to transfer.

### **IV. GENERAL ALLEGATIONS**

14. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

#### **PLAINTIFFS**

15. Zoloft is primarily marketed as an antidepressant medication but was approved for use in the United States by the FDA for treatment of Major Depressive Disorder (MDD, December 30, 1991; Obsessive-Compulsive Disorder (OCD), October 28, 1996; for children

with OCD, October 1997; Panic Disorder, July 1997; Acute Post Traumatic Stress Disorder (PTSD), December 7, 1999; and for chronic, long term PTSD, August 16, 2001; Premenstrual Dysphoric Disorder, May 20, 2002; and Social Anxiety Disorder, February 10, 2003.

16. In 2005, Zoloft was the most prescribed antidepressant drug on the US retail market with almost 27 million prescriptions dispensed. In 2005, Zoloft's sales totaled \$3.3 billion.

17. Had the Mother Plaintiff been adequately warned that Zoloft could cause congenital birth defects if ingested during pregnancy, she would not have taken the drug.

18. When the Minor Plaintiff was born, Minor Plaintiff was suffering from congenital birth defects which required extensive medical treatment.

19. The defects suffered by the Minor Plaintiff were a direct result of Mother Plaintiff's ingestion of Zoloft during her pregnancy in a manner and dosage recommended and prescribed by Mother Plaintiff's doctor.

## **DEFENDANTS**

20. The drug "sertraline hydrochloride" was and is advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold, and tested by Defendants, their predecessors in interest and subsidiaries, under the trade name Zoloft® and is a member of a class of drugs known as "selective serotonin reuptake inhibitors" or "SSRIs."

21. Zoloft was first approved for use in the United States by the FDA in 1991 for the treatment of major depression in adults.

22. Under the FDA scheme, Defendants knew, as a New Drug Application applicant, that it must fully, truthfully and accurately disclose to the FDA data and information regarding a new drug's chemistry, proposed process, proposed model labeling which includes warnings

about risks and side effects, test results for the drug, results of animal studies, results of clinical studies and the drug's bioavailability, because the data and information would be relied upon by the medical community, physicians, Plaintiffs' physicians, Plaintiffs and other foreseeable prescribers and users of Zoloft once the NDA was approved.

23. Under the FDA scheme, Defendants had a duty to ensure their warnings to the medical community are and remain accurate and adequate, to conduct safety surveillance of adverse events for the drug, to report any data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug, and to update the label when new safety information was obtained.

24. Prior to the Mother Plaintiff becoming pregnant, Defendants knew or should have known that taking Zoloft during pregnancy posed risks to the developing fetus. Defendants knew or should have known that Zoloft crosses the placenta, which could have important implications for the developing fetus.

25. Prior to the Mother Plaintiff becoming pregnant, Defendants knew or should have known that children were being born with congenital birth defects, heart defects, PPHN, craniosynostosis and other similar conditions to women who took Zoloft during pregnancy.

26. Prior to the time that the Mother Plaintiff ingested Zoloft during her pregnancy, Defendants knew of the dangerous birth defects associated with Zoloft's use during pregnancy from the preclinical studies and the subsequent published studies confirming these risks. Defendants took no action to adequately warn or remedy the risks, but instead, concealed, suppressed, and failed to disclose the dangers. Even in the face of the numerous published studies, Defendants continues to fail to warn of these dangers through revised drug labeling.

27. Defendants had access to this information and knew that congenital birth defects would result from the use of Zoloft by women who became pregnant and the fact that physicians

and the consumers such as the Mother Plaintiff herein did not fully understand the risks associated with Zoloft.

28. Defendants failed to fully, truthfully and accurately disclose Zoloft data to the FDA, the Plaintiffs and the Mother Plaintiff's physicians, and as a result negligently, intentionally and fraudulently misled the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiff about the risks to a fetus associated with the use of Zoloft during pregnancy.

29. Through the Physicians' Desk Reference, drug package inserts, patient information forms, counseling warnings, literature, marketing materials and other labeling information for Zoloft, Defendants knowingly, intentionally and negligently disseminated incomplete, inaccurate, and/or misleading warnings and information about the true risks to a fetus when Zoloft is ingested during pregnancy, which misled the medical community, physicians and the Mother Plaintiff's physicians.

30. At all times material hereto, Defendants knew or should have known that most physicians were not aware of or did not fully appreciate the seriousness of the congenital birth defect risks associated with use of Zoloft and that, consequently, there was a widespread tendency for physicians to prescribe Zoloft for use to women of childbearing potential. Consequently, Defendants knew or should have known that the warnings and labels, including but not limited to, package inserts and the Physician's Desk Reference monograph for Zoloft, did not adequately inform physicians about the birth defects risks associated with Zoloft.

31. Defendants failed to warn physicians and the Mother Plaintiff herein adequately about the congenital birth defect risks associated with Zoloft, despite the fact that Defendants knew that physicians, the medical community, the Plaintiffs, and others similarly situated relied

on Defendants to disclose what it knew or should have known from a prudent review of the information that it possessed or to which it had access.

32. Because of the misleading information that Defendants provided to physicians, the Plaintiffs and the FDA about the true congenital birth defect risks associated with the use of Zoloft and because of the failure of Defendants to adequately inform physicians generally, including the Mother Plaintiff's physicians, about the true birth defect risks associated with the use of Zoloft the Mother Plaintiff's physicians never informed her of any congenital birth defects risks associated with Zoloft. Indeed, it is believed that Defendants represented to physicians that Zoloft was safe for use by women of childbearing years and their unborn children.

33. Defendants knew, or should have known, that the warnings, including but not limited to, the label and package insert for Zoloft did not disclose the true risks of birth defects from the use of Zoloft. Defendants failed to use reasonable care to modify the warnings, including but not limited to, the label and package insert for Zoloft in order to warn physicians adequately about the true congenital birth defect risks from the use of Zoloft by women who became pregnant.

34. During the entire time Zoloft has been on the market in the United States, FDA regulations have required Defendants to issue stronger warnings whenever there existed reasonable evidence of an association between a serious risk and Zoloft. The regulations specifically state that a causal link need not have been proven to issue the new warnings. Further, the regulations explicitly allowed Defendants to issue such a warning without prior FDA approval.

35. Thus, prior to the Mother Plaintiffs pregnancy, Defendants had the knowledge, the means, and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between Zoloft and congenital birth defects, heart



defects, PPHN, craniosynostosis and other related conditions, through all means necessary, including, but not limited to, labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements, and promotional materials, etc. Defendants breached this duty.

36. Despite having extensive knowledge of the extreme risks associated with the Zoloft, as well as the absolute duty to properly and adequately warn foreseeable users, Defendants never approached the FDA to alter the label for Zoloft so that they properly and adequately warned of the risks of birth defects associated with the drug.

37. Defendants failed to disclose adequately the increased risk of congenital birth defects of Zoloft to the medical community and the Plaintiffs. Defendants were aware that their failure to disclose this information to the medical community and the Plaintiffs would result in serious injury and/or death to the children or unborn fetus of women who were prescribed Zoloft by a physician who was not aware of this information. By failing to disclose this information to the medical community and the Plaintiffs, Defendants acted in willful, wanton and outrageous manner and with evil disregard of the rights of the Plaintiffs and this conduct caused serious and permanent injuries to the Plaintiffs.

38. Defendants, their agents, servants and employees acting in the course and scope of their employment, negligently and carelessly breached their duties to the medical community, Plaintiff's physicians, Plaintiffs and other foreseeable users similarly situated, which breaches of duty include, but are not limited to:

- a) failing to ensure Zoloft warnings to the medical community, physicians, the Mother Plaintiffs physicians and Plaintiffs were accurate and adequate, despite having extensive knowledge of the risks associated with the drug;
- b) failing in their obligation to provide the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs with adequate and clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products;

- c) failing to conduct post market safety surveillance and report that information to the medical community, physicians, the Mother Plaintiffs physicians and Plaintiffs;
- d) failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, Mother Plaintiffs physicians, and Plaintiffs to the dangerous risks of Zoloft;
- e) failing to continually monitor, test, and analyze data regarding safety, efficacy and the prescribing practices for Zoloft;
- f) failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs;
- g) failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;
- h) failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy, or safety of Zoloft;
- i) failing to disclose the results of the testing and other information in their possession regarding the possibility that Zoloft can interfere with the proper development of an unborn fetus;
- j) failing to warn adequately the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs of the dangers of using Zoloft during pregnancy, including the risk of congenital birth defects;
- k) representing that Zoloft was safe for use during pregnancy when, in fact, Defendants knew or should have known that it was unsafe for this use and that Zoloft was associated with congenital birth defects;
- l) promoting and marketing Zoloft for use with pregnant women, despite the fact that Defendants knew or should have known that Zoloft was associated with an increased risk of congenital abnormalities;
- m) promoting and marketing Zoloft as safe and effective for use with pregnant women when, in fact, it was unsafe;
- n) promoting and marketing Zoloft for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising and selling Zoloft in a zealous and unreasonable way, without regard to the potential danger that it poses for an unborn fetus;
- o) failing to independently monitor their sales of Zoloft and the medical literature, which would have alerted them to the fact that Zoloft was widely over-prescribed to women of childbearing potential as a result of inadequate warnings, including those in the package inserts and PDR monographs for Zoloft, and as a result of the over-promotion of the drug;
- p) failing to act as a reasonably prudent drug manufacturer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, , marketing, packing, producing, promoting, processing, researching, selling and testing of Zoloft; and/or

- q) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zolofit use.

39. As a direct and proximate result of Defendants' actions, upon information and belief, Mother Plaintiffs prescribing physicians were unaware, and could not reasonably know, or through reasonable diligence could not have reasonably known, that Zolofit exposed the Plaintiffs to the risks and injuries alleged herein, and that those risks were the direct and proximate result of Defendants' acts or omissions.

### **INJURIES**

40. As a direct and proximate result of the conduct of Defendant as described herein and as a result of the Mother Plaintiff's ingestion of Zolofit, the Minor Plaintiff suffered from physical injuries and congenital birth defects including: bladder exstrophy, epispadias, dorsal chordee, macrocephaly, and other related conditions which caused him to suffer significant pain and suffering from the moment of his birth.

41. The Minor Plaintiff's serious injuries were the foreseeable and proximate result of Defendants' acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, physicians, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

42. As a direct and proximate result of the conduct of Defendants as described herein, Plaintiffs have suffered medical, nursing, hospital, pharmacy, rehabilitative and related costs and expenses for the Minor Plaintiff's injuries, care and lost wages, lost earning capacity, economic losses, and other damages for which it is entitled to compensation. These injuries and damages were the foreseeable and proximate result of Defendants' acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete,

false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Plaintiffs.

43. Plaintiffs, as result of the Mother Plaintiff's ingestion of Zoloft and as a direct and proximate result of the conduct of Defendants described herein, have suffered, and will suffer in the future, great emotional pain, mental anguish and other serious injury and loss, including loss of consortium, services, support, companionship, society, love and affection. These injuries and damages were the foreseeable and proximate result of Defendants' acts and/or omissions, including, but not limited to, dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information to the medical community, Mother Plaintiff's physicians, pharmacists and Mother Plaintiff.

44. The Defendants are liable to the Plaintiffs for all general, special and punitive damages, as well as delay damages, and other relief to which it is entitled to by law.

#### **V. CLAIMS FOR RELIEF**

45. The Plaintiffs set forth the following statements and claims in the alternative such that the sufficiency of this Complaint shall not be defeated by an inconsistency or insufficiency (if any) among anyone or more of the alternative statements or claims.

#### **COUNT ONE – STRICT PRODUCT LIABILITY - FAILURE TO WARN** **(PLAINTIFFS vs. DEFENDANTS)**

46. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

47. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the appropriate use of Zoloft to the Plaintiffs and the Mother Plaintiff's prescribing physicians.

48. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that the warnings and other clinically relevant information and data which it distributed regarding the risks of congenital birth defects associated with the use of Zoloft were inadequate.

49. Plaintiffs, and the Mother Plaintiff's prescribing physicians, did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to them or to their physicians.

50. Defendants had a continuing duty to provide consumers, including Plaintiffs and their physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Zoloft as it became or could have become available to Defendants.

51. Defendants manufactured, marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Zoloft in the stream of commerce, to health care providers empowered to prescribe and dispense Zoloft to consumers, including Mother Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omissions and affirmative misstatements, Defendants misled the medical community about the risks and benefits of Zoloft, which resulted in injury to Plaintiffs.

52. Despite the fact that Defendants knew or should have known that Zoloft caused unreasonable and dangerous side effects, including congenital birth defects, it continued to manufacture, market, promote, distribute, and sell Zoloft without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

53. Defendants knew or should have known that consumers and Plaintiffs specifically, would foreseeably and needlessly suffer injury as a result of the Defendants' failures.

54. Defendants breached their duty to provide timely and adequate warnings, instructions, and information, in the following particulars:

- a) failing to ensure Zolofit warnings to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs were accurate and adequate despite having extensive knowledge of the risks associated with Zolofit;
- b) failing in their obligation to provide the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs with adequate clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zolofit, and/or that there existed safer and more or equally effective alternative drug products;
- c) failing to conduct post market safety surveillance and report that information to the medical community, the Mother Plaintiff's physicians, and Plaintiffs;
- d) failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the medical community, the Mother Plaintiff's physicians, and Plaintiffs to the dangerous risks of Zolofit, including, among other things, the association with congenital birth defects;
- e) failing to continually monitor, test, and analyze data regarding safety, efficacy, and prescribing practices of their marketed drugs, including Zolofit;
- f) failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Zolofit to the medical community, the Mother Plaintiff's physicians, and Plaintiffs;
- g) failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, congenital birth defects of Zolofit;
- h) failing to periodically review all medical literature regarding Zolofit and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy, or safety of Zolofit;
- i) failing to disclose the results of the testing and other information in their possession regarding the possibility that Zolofit can interfere with the proper development of an unborn fetus;
- j) failing to warn adequately the medical community, the general public, and Plaintiffs of the dangers of using Zolofit during pregnancy, including the risk of congenital birth defects; and/or
- k) representing that Zolofit was safe for use during pregnancy, when in fact, Defendants knew or should have known that Zolofit was unsafe for this use and that Zolofit was associated with congenital birth defects.

55. Defendants continued to aggressively manufacture, market, promote, distribute, and sell Zoloft, even after it knew or should have known of the unreasonable risks of congenital birth defects from Zoloft.

56. Defendants had an obligation to provide Plaintiffs and the Mother Plaintiffs physicians with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there existed safer and more or equally effective alternative drug products.

57. By failing to provide Plaintiffs and the Mother Plaintiff's physicians with adequate, clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or to inform them that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

58. By reason of the injuries sustained to Minor Plaintiff, Mother Plaintiff has suffered excruciating pain, emotional distress, incurred expenses, including but not limited to pecuniary injuries, and medical expenses which were necessitated by reason of the aforesaid negligence and carelessness.

59. As a direct and proximate result of the actions and inactions of Manufacturing Defendants as set forth above, Plaintiffs were exposed to Zoloft, as a result suffered, and continue to suffer, the injuries and damages, as set forth herein.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT TWO - STRICT PRODUCT LIABILITY - DESIGN DEFECT  
(PLAINTIFFS vs. DEFENDANTS)**



60. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

61. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts. Defendants manufactured, marketed, promoted, distributed, and sold Zolofit in the stream of commerce which was:

- a) unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;
- b) defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Zolofit;
- c) defective in design, making use of Zolofit more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with Plaintiff's underlying condition;
- d) defective in design, making use of Zolofit more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;
- e) defective in design in that Zolofit contained insufficient, incorrect, and defective warnings in that it failed to alert physicians and users, including Plaintiffs, of the risks of adverse effects; and/or
- f) defective in design in that Zolofit was not safe for its intended use and was inadequately tested.

62. Defendants knew and intended that Zolofit would be used by consumers, including the Mother Plaintiff, without any inspection for defects, and that the Mother Plaintiff and her physicians would rely upon the representations made by Defendants on Zolofit's product labels and otherwise.

63. Prior to the, sale, and distribution of Zolofit, Defendants knew, or was reckless in not knowing, that Zolofit was in a defective condition.

64. The Mother Plaintiff used Zolofit for its intended purpose and could not have discovered any defect therein through the exercise of due care.



65. At the time that Defendants manufactured, marketed, promoted, distributed, and sold Zoloft there existed safer and more or equally effective alternative drug products.

66. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiffs were exposed to Zoloft, and as a result, suffered, and continue to suffer, injuries and damages, as set forth herein.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT THREE – NEGLIGENCE  
(PLAINTIFFS vs. DEFENDANTS)**

67. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

68. Defendants are liable to Plaintiffs pursuant to state common law and/or state Product Liability Acts due to their negligent advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, marketing, packing, producing, promoting, processing, researching, selling and testing Zoloft.

69. At all times mentioned herein, Defendants were under a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, , marketing, packing, producing, promoting, processing, researching, selling, and testing Zoloft to ensure that use of Zoloft did not result in avoidable injuries.

70. At all times relevant to this lawsuit, Defendants owed a duty to consumers, including Plaintiffs and their health care providers, to assess, manage, and communicate the

risks, dangers, and adverse effects of Zoloft, and to warn the medical community, consumers, the Plaintiffs, and the Mother Plaintiffs physicians of those risks, dangers, and adverse effects.

71. Defendants' duties included, but were not limited to, carefully and properly advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, marketing, packing, producing, promoting, processing, researching, selling, and testing Zoloft, which was placed in the stream of commerce, and providing adequate information regarding the appropriate use of Zoloft.

72. Defendants negligently and carelessly breached the above-described duties to Plaintiffs by committing negligent acts and/or omissions, including, but not limited to, the following:

- a) failing to ensure Zoloft's warnings to the medical community, physicians, the Mother Plaintiff's physicians, and Plaintiffs were accurate and adequate, despite having extensive knowledge of the risks associated with Zoloft;
- b) failing in their obligation to provide the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs with adequate and clinically relevant information, and data and warnings regarding the adverse health risks associated with exposure to Zoloft, and/or that there c) failing to conduct post market safety surveillance and report that information to the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs;
- d) failing to include adequate warnings and/or provide adequate and clinically relevant information and data that would alert the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs to the dangerous risks of Zoloft;
- e) failing to continually monitor, test, and analyze data regarding safety, efficacy, and the prescribing practices for Zoloft;
- f) failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Zoloft to the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs;
- g) failing to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, congenital birth defects of Zoloft;
- h) failing to periodically review all medical literature regarding Zoloft and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy, or safety of Zoloft;

- i) failing to disclose the results of the testing and other information in their possession regarding the possibility that Zolofit can interfere with the proper development of an unborn fetus;
- j) failing to warn adequately the medical community, physicians, the Mother Plaintiffs physicians, and Plaintiffs of the dangers of using Zolofit during pregnancy, including the risk of congenital birth defects;
- k) representing that Zolofit was safe for use during pregnancy when, in fact, Defendants knew or should have known that Zolofit was unsafe for this use and that Zolofit was associated with congenital birth defects;
- i) promoting and marketing Zolofit for use with pregnant women, despite the fact that the Defendants knew or should have known that Zolofit was associated with an increased risk of congenital abnormalities;
- m) promoting and marketing Zolofit as safe and effective for use with pregnant women when, in fact, it was unsafe;
- n) promoting and marketing Zolofit for non-approved (off-label) uses and/or illegally over-promoting, marketing, advertising, and selling Zolofit in a zealous and unreasonable way, without regard to the potential danger that it posed for an unborn fetus;
- o) failing to independently monitor their sales of Zolofit and the medical literature, which would have alerted them to the fact that Zolofit was widely over-prescribed to women of childbearing potential as a result of inadequate warnings in the package inserts and PDR monographs for Zolofit, and as a result of the over-promotion of Zolofit;
- p) failing to act as a reasonably prudent drug manufacturer in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, , marketing, packing, producing, promoting, processing, researching, selling, and testing Zolofit;
- q) failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with Zolofit's use;
- r) failing to use ordinary care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, , marketing, packing, producing, promoting, processing, researching, selling, and testing Zolofit so as to reveal and communicate the risk of congenital birth defects to the medical community, the Mother Plaintiff s physicians, and Plaintiffs;
- s) failing to accompany Zolofit with adequate information that would alert the medical community, the Mother Plaintiffs physicians, and Plaintiffs to the potential adverse side effects associated with the use of Zolofit and the nature, severity, and duration of such adverse effects;
- t) failing to conduct adequate post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses to determine and communicate the safety profile and side effects of Zolofit;
- u) continuing to promote the safety and effectiveness of Zolofit, while downplaying their risks, even after Defendants knew or should have known of the risks of Zolofit;
- v) failing to provide consumers, such as Plaintiffs and Plaintiffs' physicians, with scientific data which indicated that Zolofit was unreasonably dangerous, and that

- there were no women of childbearing potential and/or pregnant women in whom the benefits of Zoloft outweighed the risks;
- w) being careless and negligent in that Defendants knew or should have known that Zoloft was a substance that would be actively transported through the placenta during pregnancy and could inhibit the health and development of the fetus;
  - x) negligently and carelessly promoting Zoloft as safe and effective for use with women of childbearing potential and/or pregnant women when, in fact, it was unsafe;
  - y) negligently and carelessly over-promoting Zoloft in a zealous and unreasonable way, without regard to the potential danger that it posed to an unborn fetus; and/or
  - z) negligently and carelessly failing to act as a reasonably prudent drug manufacturer, distributor, marketer, promoter, or seller would under same or similar circumstances.

73. Although Defendants knew or should have known that Zoloft caused unreasonably dangerous side effects, including congenital birth defects, Defendants continued to market Zoloft, despite the fact there were safer and more or equally effective alternative drug products.

74. Defendants knew or should have known that consumers, such as Plaintiffs, would suffer injury as a result of Defendants' failure to exercise ordinary care, as described above.

75. The conduct of Defendants were a direct and proximate cause of Plaintiffs' injuries. Defendants knew or should have known that Zoloft could be dangerous and unsafe for pregnant women and the developing fetus.

76. As a direct and proximate result of the negligent acts and/or omissions of Defendants as set forth above, Plaintiffs suffered, and will continue to suffer into the future, injuries and damages, as set forth herein.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT FOUR - NEGLIGENT DESIGN  
(PLAINTIFFS vs. DEFENDANTS)**

77. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

78. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the negligent design of Zoloft.

79. At all times relevant to this lawsuit, Defendants owed a duty to consumers, including Plaintiffs and their health care providers, to exercise reasonable care in the design of Zoloft.

80. Defendants negligently and carelessly breached this duty of care to Plaintiffs because it designed Zoloft which:

- a) was and is unreasonably defective in design because it is a teratogenic compound that unreasonably increased the risks of congenital birth defects;
- b) was and is defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks which exceeded the benefits of Zoloft;
- c) was and is defective in design, making use of Zoloft more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the Mother Plaintiffs underlying condition;
- d) was and is defective in design, making use of Zoloft more dangerous than the ordinary consumer would expect and more dangerous than other risks associated with like products;
- e) was and is defective in design in that it contained insufficient, incorrect and defective warnings in that it failed to alert physicians and users, including the Mother Plaintiff of the risks of adverse effects;
- f) was and is defective in design in that it was not safe for its intended use and was inadequately tested;
- g) was and is defective in design because its risks exceeded any benefit of Zoloft; and/or
- h) failed to act as a reasonably prudent drug manufacturer, seller, promoter, distributor, or marketer would have acted with respect to the design of Zoloft.

81. As a direct and proximate result of the negligent acts and/or omissions of the Defendants, Plaintiffs suffered injuries and damages, as set forth herein.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, costs of suit in an amount to be determined upon the trial of this matter.

**COUNT FIVE - FRAUD, MISREPRESENTATION AND SUPPRESSION  
(PLAINTIFFS vs. DEFENDANTS)**

82. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

83. Defendants are liable to Plaintiffs under the state common law and/or state Product Liability Acts for fraudulently, intentionally, and/or negligently misrepresenting to the public, and to Plaintiffs, both directly and by and through the Mother Plaintiffs prescribing physicians, the safety and effectiveness of Zolofit when used by women of childbearing potential, and/or fraudulently, intentionally, and/or negligently concealing, suppressing or omitting material, adverse information regarding the safety and effectiveness of Zolofit when used by women of childbearing potential.

84. Defendants' fraudulent, intentional, and/or negligent material misrepresentations and omissions regarding the safety and efficacy of Zolofit and of Zolofit's side effects, including the risk of congenital birth defects, were communicated to Plaintiffs directly through promotional materials, advertising, product inserts, and the monograph provided with Plaintiffs prescription with the intent that the Mother Plaintiff use Zolofit. The safety and efficacy of Zolofit was also fraudulently, intentionally, and/or negligently misrepresented to the Mother Plaintiffs prescribing physician with the intent that such misrepresentations would cause Zolofit to be prescribed to the Mother Plaintiff.

85. Defendants either knew or should have known that the material representations it was making regarding Zolofit's safety, efficacy, and side effects were false.

86. Defendants fraudulently, intentionally, and/or negligently made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire to induce the Mother Plaintiff, the Mother Plaintiff's



physicians, and the consuming public to use and prescribe Zoloft. Defendants fraudulently, intentionally, and/or negligently knew or should have known that the Mother Plaintiff, the Mother Plaintiffs physician, and the consuming public would rely on such material misrepresentations and/or omissions in selecting Zoloft for the treatment of the Mother Plaintiff.

87. Defendants knew or should have known that the Mother Plaintiff and the Mother Plaintiff's physician would rely upon their false representations and/or omissions.

88. Defendants made these material misrepresentations and/or omissions and actively concealed adverse information at a time when they, their agents and/or their employees knew or should have known that Zoloft had defects, dangers, and characteristics that were other than what had been represented to the medical community and the consuming public, including the Plaintiffs herein. Those misrepresentations and omissions further include, but are not limited to, the following particulars:

- a) Defendants failed to disclose or concealed that their pre-clinical and clinical testing, and post-marketing surveillance was inadequate to determine the safety and side effects of Zoloft;
- b) Defendants failed to disclose or concealed data showing that Zoloft increased the risk of congenital birth defects;
- c) Defendants failed to include adequate warnings with Zoloft about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including, without limitation, the increased risk of congenital birth defects, other injuries and death, either compared to the use of alternative drug products in its class or compared to the use of no drug products; and/or
- d) Defendants concealed and continue to conceal past and present facts, including that as early as the 1990's, Defendants were aware of and concealed their knowledge of an association between the use of Zoloft and dangerous side effects, including the increased risk of congenital birth defects, from the consuming public, including Plaintiffs and the Mother Plaintiff's physicians.

89. Defendants' material misrepresentations and/or active concealment, suppression, and omissions were perpetuated directly and/or indirectly by Defendants, their sales representatives, employees, distributors, agents, and/or detail persons, through the databases,

printouts, monographs, and other information drafted, prepared, marketed, sold, and supplied by Defendants, their sales representatives, employees, distributors, agents, and/or detail persons.

90. Defendants' material misrepresentations and/or active concealment, suppression, and omissions constitute a continuing tort.

91. Through its product inserts, Defendants continued to misrepresent the potential risks and complications associated with Zolofit.

92. Defendants had a post-sale duty to warn physicians and Plaintiffs about the potential risks and complications associated with Zolofit it manufactured and sold in a timely manner.

93. Defendants fraudulently, intentionally, and/or negligently misrepresented the safety and efficacy of Zolofit in their labeling, advertising, product inserts, promotional materials, or other marketing.

94. If Plaintiffs and the Mother Plaintiffs physicians had known the true facts concerning the risks of Zolofit, in particular, the risk of congenital birth defects, it would not have prescribed and used Zolofit, and would have instead prescribed and used one of the safer alternatives, or no drug.

95. Plaintiffs' and Plaintiffs physicians' reliance upon the Defendants' material misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Zolofit, while Plaintiffs and Plaintiff's physicians were not in a position to know the true facts, and because Defendants overstated the benefits and safety of Zolofit, and concomitantly downplayed the risks of its use, including congenital birth defects, thereby inducing the Mother Plaintiff and the Mother Plaintiff's physician to use Zolofit, in lieu of other, safer alternatives, or no drug at all.



96. As a direct and proximate result of the Plaintiffs' and the Mother Plaintiffs physicians' reliance on Defendants' misrepresentations and concealment concerning the risks and benefits of Zoloft, Plaintiffs suffered injuries and damages, as set forth herein.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT SIX - CONSTRUCTIVE FRAUD  
(PLAINTIFFS vs. DEFENDANTS)**

97. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

98. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for constructive fraud in the distribution, and sale of Zoloft.

99. At the time Zoloft was manufactured, distributed, and sold by Defendants to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Zoloft, which knowledge was not possessed by Plaintiffs or the Mother Plaintiff's physicians, and Defendants thereby held a position of superiority over Plaintiffs.

100. Through their unique knowledge and expertise regarding the defective nature of Zoloft, and through their marketing statements to physicians and patients in advertisements, promotional materials, and other communications, Defendants professed that it was in possession of facts demonstrating that Zoloft was safe and effective for its intended use and was not defective.

101. Defendants' representations to the Mother Plaintiffs physicians were made to induce the purchase of Zoloft, and Plaintiffs and their physicians relied upon those statements when purchasing and administering Zoloft.

102. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their physicians and engaged in constructive fraud in their relationship.

103. Plaintiffs and the Mother Plaintiffs physicians reasonably relied on Defendants' representations.

104. As a direct and proximate result of Defendants' constructive fraud, Plaintiffs have suffered injuries and damages, as set forth herein.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT SEVEN - BREACH OF EXPRESS AND IMPLIED WARRANTIES  
(PLAINTIFFS vs. DEFENDANTS)**

105. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

106. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for the breach of express and implied warranties of Zoloft.

107. At all times hereinafter mentioned, upon information and belief, Defendants, by directly and indirectly advertising, marketing, and promoting Zoloft for the treatment of women, including women of childbearing potential and pregnant women, and by placing Zoloft in the stream of commerce knowing that Zoloft would be prescribed to pregnant women in reliance upon the representations or omissions of Defendants, expressly warranted to all foreseeable users of Zoloft, including the Mother Plaintiff and the Mother Plaintiffs physicians, that Zoloft

was safe and effective for the treatment of women during pregnancy and without significant risk to the fetus.

108. Defendants impliedly warranted in distributing, selling, advertising, marketing, and promoting Zoloft to all foreseeable users, including the Mother Plaintiff and the Mother Plaintiffs physicians, that Zoloft was safe and effective for the purposes for which it had been placed in the stream of commerce by Defendants, including for the treatment of pregnant women, and that Zoloft was reasonably safe, proper, merchantable, and fit for its intended purpose, including for the treatment of pregnant women and without significant risk to the fetus.

109. At all times relevant hereto, Plaintiffs and the Mother Plaintiffs physicians relied upon the aforesaid express and implied warranties by Defendants.

110. The Mother Plaintiffs use of Zoloft, and the Mother Plaintiffs physicians' prescribing of Zoloft was consistent with the purposes for which Defendants directly and indirectly advertised, marketed, and promoted Zoloft, and the Mother Plaintiffs use of Zoloft, and the Mother Plaintiffs physicians' prescribing of Zoloft was reasonably contemplated, intended, and foreseen by Defendants at the time of the distribution and sale of Zoloft by Defendants, and, therefore, the Mother Plaintiffs use of Zoloft was within the scope of the above-described express and implied warranties.

111. Defendants breached the aforesaid express and implied warranties because Zoloft was not safe and effective for the treatment of women during pregnancy because it exposed the developing fetus to a significant risk of serious injury, and because the Mother Plaintiffs use of Zoloft for treatment during her pregnancy caused the Minor Plaintiff's injuries.

112. As a direct and proximate result of Defendants' breach of express and implied warranties, Plaintiffs suffered injuries and damages, as set forth herein.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendants for an amount in excess of \$ 75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT EIGHT - GROSS NEGLIGENCE/MALICE  
(PLAINTIFFS vs. DEFENDANTS)**

113. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

114. Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts for gross negligence and/or malice.

115. While performing each of the acts and omissions previously set forth in this Complaint, Defendants actually knew of the defective nature of their products and the inadequacy of their warnings as set forth herein, yet Defendants continued to author, create, design, distribute edit, manufacture, market, sell and provide their products in their defective condition so as to maximize sales and profits at the expense of Plaintiffs' health and the health of the consuming public.

116. The acts and omissions of Defendants involved an extreme degree of risk, given the probability and magnitude of causing harm to Plaintiffs and others.

117. The Defendants had actual, subjective awareness of the risk of injury posed by Zolofit and the Zolofit information and warnings, to consumers such as Plaintiffs. Moreover, a reasonable company in the position of the Defendants would have been aware of the risk of injury posed to consumers by the use of Zolofit and the Zolofit information and warnings. Yet, Defendants proceeded in conscious disregard to the rights, safety, and welfare of Plaintiffs.

118. The acts and omissions of Defendants demonstrate that they did not care about the peril it subjected upon Plaintiffs such that their conduct was grossly negligent.

119. Further, the wrongs done by the Defendants were aggravated by the kind of malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiffs for which the law allows the imposition of exemplary damages in that the Defendants' conduct:

- a) when viewed objectively from the Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and the Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; and/or
- b) included a material representation that was false, with the Defendants knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

120. Plaintiffs therefore seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

121. Plaintiffs also allege that the acts and omissions of the Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish the Defendants for their conduct and which would deter other similar defendants from engaging in such misconduct in the future.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT NINE - LOSS OF CONSORTIUM AND PECUNIARY LOSS  
(PLAINTIFFS vs. DEFENDANTS)**

122. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

123. The Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts.

124. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiffs were exposed to Zolofit and the Mother Plaintiff has suffered, and will continue to suffer, the past and future injuries, damages, and losses as a result of the injuries sustained to Minor Plaintiff as set forth herein.

125. The Defendants are liable to Plaintiffs for all general, special, and punitive damages, delay damages, and other relief to which it is entitled by law.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT TEN - NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS  
(PLAINTIFFS vs. DEFENDANTS)**

126. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

127. The Defendants are liable to Plaintiffs under state common law and/or the applicable state Product Liability Acts.

128. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiffs were exposed to Zolofit and the Plaintiffs have suffered, and will continue to suffer, the past and future injuries, damages, and losses as a result of the Minor Plaintiff's injuries, as set forth herein.

129. The negligent actions of the Defendants has caused the Mother Plaintiff's serious emotional distress as a consequence of having witnessed the pain and suffering of her daughter from the wrongful conduct of the Defendants who knew of should have known and foreseen that their conduct would cause such distress.

130. The Defendants are liable to Plaintiffs for all general, special, and punitive damages, delay damages, and other relief to which it is entitled by law.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

**COUNT ELEVEN - PUNITIVE DAMAGES  
(PLAINTIFFS vs. DEFENDANTS)**

131. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

132. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provision, because the Defendants' actions were reckless and without regard for the public's safety and welfare. The Defendants knowingly withheld, concealed or misrepresented the risks and dangers of Zoloft and the Zoloft information and warnings, including the risk of congenital birth defects, from both the medical community and the public at large, including Plaintiffs, their physicians and pharmacists. The Defendants downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of Zoloft, including congenital birth defects, despite information demonstrating Zoloft was unreasonably dangerous and in conscious disregard of the risk of serious injury posed to Plaintiffs by these known misrepresentations and/or omissions.

133. Plaintiffs are entitled to punitive damages, pursuant to state common law or the applicable statutory provision, because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendants misled the medical community and the public at large, including Plaintiffs, their physicians and pharmacists, by making false representations about and concealing pertinent information regarding Zoloft and its information and warnings. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Zoloft, including congenital birth defects, despite information demonstrating the product was unreasonably dangerous.

134. At all times material hereto, the Defendants had a duty to exercise reasonable care in the advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, marketing, packing, producing, promoting, processing, researching, selling, and/or testing Zoloft.

135. The conduct of the Defendants in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, , marketing, packing, producing, promoting, processing, researching, selling, and/or testing Zoloft, and in failing to warn Plaintiffs, the Mother's Plaintiff physicians, pharmacists and other members of the public of the dangers inherent in the use of Zoloft, which were known to the Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

136. The Defendants knew that Zoloft had unreasonably dangerous risks and caused serious side effects of which Plaintiffs, their physicians and pharmacists would not be aware. The Defendants nevertheless advertised, analyzed, assembled, compounded, designed, developed, distributed, formulated, inspected, labeled, manufactured, marketed, packaged, produced,



promoted, processed, researched, sold, and tested Zolofit knowing that there were safer methods and products available.

137. The Defendants' actions were performed willfully, deliberately, intentionally, and with reckless disregard for the rights and safety of Plaintiffs and the public and caused substantial financial injury.

138. The conduct of the Defendants, undertaken with knowledge, for these purposes, evinces gross negligence and a willful, wanton, and conscious disregard for the rights and safety of consumers, including the Plaintiffs, and as a direct and proximate result of the Defendants' actions and inactions, Plaintiffs suffered injuries due to Defendants' disregard for Plaintiffs' rights and safety, and therefore, Plaintiffs are entitled to an award of punitive damages from Defendants.

**WHEREFORE**, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of \$75,000.00, compensatory and punitive damages, delay damages, and costs of suit in an amount to be determined upon the trial of this matter.

#### **VI. JURY DEMAND**

145. Plaintiffs demand that all issues of fact in this case be tried to a properly empanelled Jury.

#### **VII. CONCLUSION AND PRAYER**

WHEREFORE, Plaintiffs request trial by jury and that the Court grants them the following relief against the Defendants, on all counts of this Complaint, including:

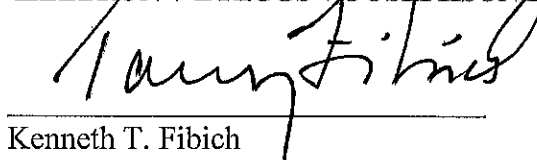
- (A) Money Damages representing fair, just, and reasonable compensation for their respective common law and statutory claims in excess of \$75,000.00;
- (B) Lost Wages;
- (C) Punitive and/or Treble Damages pursuant to state law;
- (D) Attorneys' fees;

- (E) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;
- (F) Costs of suit and expenses;
- (G) Delay Damages; and
- (H) Such other relief as is deemed just and appropriate.

Dated: September 23, 2013

Respectfully Submitted,

**FIBICH ♦ HAMPTON  
LEEBRON ♦ BRIGGS ♦ JOSEPHSON LLP**



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